

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

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INSIGHT CHICAGO, INC., D/B/A	:
INSIGHT HOSPITAL AND MEDICAL	:
CENTER CHICAGO,	:
	:
Plaintiff,	:
	:
v.	: Case No. 23 cv 14328
	:
XAVIER BECERRA,	:
SECRETARY OF UNITED STATES DEPARTMENT	:
OF HEALTH AND HUMAN SERVICES,	:
in his official capacity, and	:
	:
CAROLE JOHNSON, ADMINSTRATOR OF THE	:
HEALTH RESOURCES AND	:
SERVICES ADMINISTRATION,	:
in her official capacity,	:
	:
Defendants.	:
-----X	

COMPLAINT FOR DECLARATORY JUDGMENT, INJUNCTIVE RELIEF,
AND MANDAMUS

Plaintiff Insight Chicago, Inc. d/b/a Insight Hospital & Medical Center Chicago (“Plaintiff” or “Insight”), for its Complaint for Declaratory Judgment, Injunctive Relief, and Mandamus (“Complaint”) against Defendants Xavier Becerra, Secretary of the United States Department of Health and Human Services, in his official capacity (“Secretary Becerra” or the “Secretary”), and Carole Johnson, Administrator of the Health Resources Services Administration, in her official capacity (“Administrator Johnson” or the “Administrator”) (the Secretary and the Administrator, collectively, “Defendants”), states as follows:

INTRODUCTION

1. This action seeks declaratory judgment, injunctive relief, and mandamus to prevent Defendants' unlawful attempt to terminate Insight – a nonprofit disproportionate share hospital that serves the South Side of Chicago and its uninsured, isolated, and/or medically vulnerable population – from the Section 340B drug pricing program, which provides significant savings on outpatient drugs for hospitals serving at-risk communities.

2. Defendants seek to terminate Insight from the Section 340B Program by requiring Insight to recertify its eligibility under the program less than one year from its previous recertification, in violation of the clear and unambiguous statutory requirements.

3. Defendants, however, lack authority to terminate Insight from the Section 340B Program. The 340B statute requires certification and recertification by certain Covered Entities that receive assistance under federal HIV programs or funds for treating sexually transmitted diseases, but does not mandate recertification for all Covered Entities. *See* 42 U.S.C. § 256b(a)(7)(A). Moreover, Section 340B includes remedies for noncompliance by a Covered Entity that resells drugs to a person who is not a patient of the Covered Entity, but notably Congress did not authorize the Secretary to terminate a hospital's participation in the program due to an alleged untimely recertification or an alleged untimely update of a hospital's information on the Secretary's website. *See* 42 U.S.C. § 256b(d)(2).

4. Even if Insight were required to recertify its eligibility under Section 340B, Defendants failed to comply with the plain language of the statute governing recertification. Specifically, Section 340B provides that the Secretary shall not require recertification more frequently than on an annual basis. 42 U.S.C. § 256b(a)(7)(E). Defendants, however, required Insight to recertify under Section 340B within merely 357 days of Insight's previous recertification

and impeded Insight's efforts to recertify, or otherwise update its information on the Secretary's website, during the remaining eight (8) days of the one-year period.

5. Defendants then notified Insight that it would be terminated from the Section 340B Program effective October 1, 2023. Such termination would deny Insight access to the discounted drug prices available under Section 340B, thus forcing Insight to either sacrifice patient access to outpatient drugs or sharply curtail or eliminate other health services provided by a safety-net hospital.

6. The declaratory judgment, injunctive relief, and mandamus Insight seeks in this action are necessary to prevent immediate and irreparable harm to Insight and to thwart the adverse consequences that would flow to the public, namely decreased access to prescription drugs and an overall decline in available health care services for the underserved South Side of Chicago community. This is the only relief sought in this action, as Insight is not seeking monetary damages, there is no traditional legal remedy that would be adequate in place of an injunction and/or mandamus, and there is no available administrative remedy available for Section 340B recertification matters.

PARTIES

7. Plaintiff Insight, a not-for-profit hospital, is an Illinois corporation with its principal place of business located at 2525 South Michigan Avenue, Chicago, Illinois 60616.

8. Secretary Becerra is the Secretary of the Department of Health and Human Services ("HHS"), the federal agency that oversees the Health Resources and Services Administration. Secretary Becerra is named in his official capacity. References to the Secretary are meant to refer to him, to his subordinates, and to his official predecessors or successors as the context requires.

9. Administrator Johnson is the Administrator of the Health Resources and Services Administration (“HRSA”), the component of the Secretary’s agency responsible for ensuring access to health care services for people who are uninsured, isolated, or medically vulnerable, including administration of the Section 340B Program. Administrator Johnson is named in her official capacity. References to the Administrator are meant to refer to her, to her subordinates, and to her official predecessors or successors as the context requires.

JURISDICTION AND VENUE

10. This action arises under Section 340B of the Public Health Services Act, 42 U.S.C. § 265b, and the Declaratory Judgment Act, 28 U.S.C. § 2201.

11. Jurisdiction is proper under 28 U.S.C. § 1331. This Court also has jurisdiction over this original petition for a writ of mandamus under 28 U.S.C. § 1361 and under the All Writs Act, 28 U.S.C. § 1651(a).

12. Venue is proper in this judicial district under 28 U.S.C. § 1391(e)(1).

FACTUAL ALLEGATIONS

Insight and Its Patient Population

13. Insight is an acute care hospital with 412 staffed beds, including medical-surgical beds, an intensive care unit, a neonatal unit, a rehabilitation unit, and an acute mental health unit.

14. The inpatient services most in demand at Insight include internal medicine, pulmonology, and psychiatry. The most in demand outpatient services are radiology, emergency department services, and clinic visits.

15. Insight serves Chicago’s South Side, namely the Grand Boulevard and Bronzeville neighborhoods.

16. Insight is the successor to Mercy Hospital and Medical Center (“Mercy”), which has served the South Side since 1852. Indeed, Insight’s affiliate purchased Mercy out of bankruptcy and took over operations of the hospital effective June 1, 2021.

17. During 2022, Insight treated approximately 51,000 patients from these neighborhoods and the surrounding area.

18. Within its catchment area, 35% of the population lives in poverty, and the unemployment rate is approximately 21%. The median income is less than half that of the City of Chicago as a whole.

19. Thirteen percent (13%) of residents who live in the area that Insight serves are uninsured.

20. Within this area, approximately 46% of adults are obese, 14% suffer from diabetes, and 20% have asthma.

21. Health indicators for these neighborhoods – including diagnoses for invasive breast cancer, lung cancer, colorectal cancer, other cancers, asthma, hypertension, COVID-19, HIV, and sexually transmitted diseases – all exceed the average for Chicago, as do the incidence of disabilities and mortality from many chronic and infectious diseases.

22. The average life expectancy of individuals who live in the neighborhoods that Insight serves is 73 years, below the average of 77 years for the entire City of Chicago.

23. Insight is a true safety-net hospital, providing care and treatment to some of Chicago’s most vulnerable individuals who otherwise lack meaningful access to health care.

The 340B Program

24. In 1992, Congress established what is now commonly referred to as the "340B Program," as it is contained in Section 340B of the Public Health Services Act, 42 U.S.C. §265b.

25. The 340B Program allows participating hospitals and other health care providers ("Covered Entities") to purchase certain "covered outpatient drugs" from manufacturers at or below the drugs' maximum or ceiling prices. 42 U.S.C. § 256b(a)(1).

26. The pricing for drugs covered under Section 340B is dictated by a statutory formula and is typically significantly discounted from those drugs' average manufacturer prices. 42 U.S.C. § 256b(a)(1)-(2).

27. These Section 340B pricing discounts are a condition of the drug manufacturers' participation in the Medicaid program.

28. Section 340B is intended to enable Covered Entities such as hospitals that serve a disproportionate share of low-income individuals "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992).

29. Notably, the Section 340B Program does not depend on separate expenditures by the Secretary, or appropriations by Congress.

30. The 340B Program allows Covered Entities to realize savings through the purchase of discounted drugs, which savings can be used to otherwise lower the cost of providing health care and can expand free health care.

31. Defendants maintain that a Covered Entity such as a hospital that wants to take advantage of the Section 340B Program discounts is obligated to enroll in the program **and** recertify its eligibility on an annual basis.

32. Specifically, the relevant part of the Section 340B statute provides:

(E) Recertification The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

42 U.S.C. § 256b(a)(7)(E) (emphasis added).

33. Certain Covered Entities otherwise eligible to participate in the Section 340B Program, however, are not subject to the recertification requirements under 42 U.S.C. § 256b(a)(7)(E). Indeed, subsection (a)(7), entitled “Certification of certain Covered Entities” (emphasis added), sets forth a certification and recertification process that applies, as the title of implies, only to certain Covered Entities, not all.

34. Insight is not one of the entities covered by the certification process of 42 U.S.C. § 256b(a)(7).

35. The relevant part of the Section 340B statute provides:

(A) Development of process Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

42 U.S.C. § 256b(a)(7)(A) (emphasis added).

36. As such, the 340B statute requires recertification for only those Covered Entities that receive assistance under federal HIV programs (subparagraph (J) of paragraph (4)) or funds for treating sexually transmitted diseases (subparagraph (K) of paragraph (4)), but does not mandate recertification for all Covered Entities. *See* 42 U.S.C. § 256b(a)(7)(A).

37. As set forth below, Insight falls under the definition of “Covered Entity” pursuant to subparagraph (L) of paragraph (4), not subparagraphs (J) or (K) of paragraph (4).

38. Section 256b(d) of the 340B statute is entitled “Improvements in program integrity.” Subsection (2) of 256b(d), entitled “Covered entity compliance,” requires the Secretary to implement “improvements in compliance by Covered Entities.”

39. Among the required improvements is that Covered Entities “regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services.” 42 U.S.C. § 256b(d)(2)(B)(i).

40. The statute does not, however, provide that a Covered Entity may be disqualified from the 340B Program if it fails to timely provides its annual update.

41. The **only** instance specifically stated in the statute when the Secretary may disqualify a Covered Entity from participation is where “the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional.” 42 U.S.C. § 256b(d)(2)(B)(v)(II).¹

42. The 340B statute states no other instances when the Secretary may disqualify a Covered Entity from continued participation in the 340B Program.

Insight’s Participation in the Section 340B Program

43. Insight qualifies as a disproportionate share hospital, which means that it treats a disproportionate number of low-income Medicare and Medicaid patients, as measured by the hospital's disproportionate share hospital (DSH) adjustment percentage. 42 U.S.C. § 1395ww(d)(5)(F).

44. As a disproportionate share hospital, Insight is eligible to participate in the Section 340B Program as a “Covered Entity” under subparagraph (L) of paragraph (4). *See* 42 U.S.C. § 256b(a)(4)(L).

¹ Section (a)(5)(B) prohibits the resale of drugs “to a person who is not a patient of the entity.”

45. Insight has participated in the Section 340B Program since April 2008.

46. Participation in the Section 340B Program allows Insight to save considerable amounts in outpatient drug costs and reallocate the savings to other health care services, such as to fund hospital operations, support its charity care program, and provide prescription assistance to patients.

HRSA Prevents Insight from Recertifying Its Eligibility Under the Section 340B Program

47. Insight most recently completed its recertification for the Section 340B Program on September 19, 2022.

48. Under the plain terms of 42 U.S.C. § 256b(a)(7)(E), therefore, if Insight were required to recertify under the Section 340B Program for 2023 (which Insight maintains it was not), such recertification would not have been due until September 19, 2023.

49. HRSA, however, provided notice to Insight that its Section 340B recertification must be submitted no later than September 11, 2023 – eight (8) days earlier than the anniversary of its previous recertification.

50. Insight attempted to complete the recertification process before the one-year anniversary of its prior recertification, which was September 19, 2023. Specifically, six days earlier on September 13, 2023, Insight's Chief Pharmacy Officer (CPO), David Hughes, logged into the online portal, which showed that the recertification was "pending." He attempted to complete the recertification process right then, but the website gave him no option to submit Insight's recertification materials through the online portal.

51. In response, Mr. Hughes immediately contacted HRSA's Section 340B third-party administering contractor, Apexus, asking how to resolve this issue and seeking confirmation that there were no changes to Insight's 340B registration.

52. Also during the morning of September 13, 2023, Mr. Hughes called and spoke to an Apexus customer service representative, who indicated that she was communicating with HRSA to try to get them to reopen the recertification task so that Mr. Hughes could complete the recertification process on the portal.

53. Apexus responded via email on September 14, 2023, asking if Mr. Hughes had received any correspondence from HRSA in response to his prior message. He had not, but asked Apexus how to contact HRSA directly.

54. On September 15, 2023, Apexus emailed Mr. Hughes advising that it had passed on his concerns to HRSA, but that Apexus had not heard anything from HRSA.

55. Later on September 15, 2023, Mr. Hughes contacted HRSA via an email address dedicated for recertification questions and copied Apexus. In that e-mail, Mr. Hughes attempted to confirm that nothing was changing with respect to Insight's 340B registration and pleaded to be allowed to recertify. Mr. Hughes also attached to the e-mail Insight's most recent cost report, **which was the only documentation required to be submitted as part of the recertification process.**

56. As a result, HRSA had received from Insight all of the materials required for recertification under the Section 340B Program on September 15, 2023, four days prior to the one-year anniversary of Insight's previous recertification of September 19, 2022.

57. Mr. Hughes also called HRSA directly on Friday September 15 and left a message on its general voicemail requesting a call back. He called them again on Monday September 18 and left another message requesting a call back. Mr. Hughes never received an acknowledgment or call back from those voicemails.

58. On September 19, 2023, Apexus notified Insight that HRSA would terminate Insight from the 340B Program effective October 1, 2023, and that the Apexus ticket was being closed as “no further action can be done.”

59. On September 20, 2023, Insight again e-mailed HRSA detailing its efforts to submit the recertification materials.

60. Insight submitted an additional, lengthy e-mail to HRSA on September 21, 2023, providing additional information on the impact termination from the 340B Program would have on Insight’s patients and community.

61. However, on September 22, 2023, Lieutenant Commander Emeka Egwim, U.S. Public Health Service Director Office of Pharmacy Affairs (“Director Egwim”), informed Insight that HRSA would not change its decision to terminate Insight’s Section 340B participation and that the hospital could instead reapply to qualify as of January 1, 2024.

62. The next day, September 23, 2023, Insight again emailed Director Egwim, imploring him to find a way to resolve the issue without interruption to Insight’s Section 340B status. Insight also invited Director Egwim to meet to discuss potential resolutions.

63. On September 27, 2023, Insight again emailed Director Egwim, urging him to stay and withdraw the termination decision and advising that Insight would be forced to take immediate legal action if Defendants did not permit Insight’s continued participation in the 340B Program.

64. Director Egwim responded later on September 27, 2023, stating that HRSA is open to a discussion, but maintains its position to terminate Insight from the 340B Program effective October 1, 2023.

65. On September 28, 2023, Insight and its counsel participated in multiple videoconference calls with Director Egwim and/or other government officials, including multiple

attorneys from the DHS Office of General Counsel. During the last call, Insight's counsel stated the legal theories Insight would pursue in court. Mr. Hughes, of Insight, also explained how vital the 340B Program was to Insight's ongoing operations and to the community it served. Insight's counsel explained that Insight's strong preference was not to litigate, but that Insight would have no choice but to file suit if there was no resolution by 12:00 p.m. on Friday, September 29, 2023.

66. No such resolution was reached, as HRSA maintains its position to terminate Insight from the 340B Program effective October 1, 2023.

67. The impact of HRSA's actions will be immediate and will severely impact the at-risk patients who Insight serves.

68. For the fourth quarter of 2023 alone, Insight's non-participation in the 340B Program will result in approximately \$1 million in additional costs that will affect an estimated 9,700 eligible patients/encounters, including 1,000 charity care uninsured patients.

69. Without the 340B Program savings, outpatient drugs that could be acquired through the 340B Program for eight to twenty dollars will cost more than \$500. These medications include (1) cardiology medications (Eliquis, Xarleto, Jardiance), (2) diabetes treatments (insulin, oral treatments), (3) antibiotics, (4) antipsychotics and antidepressants, (5) addiction medicine treatments (Suboxone), and (6) asthma treatment (albuterol inhalers, Symbicort®).

70. As a specific example, an uninsured patient with cancer could be receiving prescription drugs for free from Insight that a manufacturer sells at \$50,000 per prescription. Insight may pay, however, only \$500 for that prescription under the 340B Program. Insight can afford to give a drug for free that costs the hospital \$500, but it cannot afford to give that drug for free when it will cost the hospital \$50,000.

71. Insight provides free medications to approximately 100 uninsured patients per month. Free medications for uninsured and/or indigent patients are funded with the savings Insight receives from participation in the 340B Program. These patients are exclusive of the 2,000 outpatient pharmacy patients to whom Insight is able to provide discounted prices for prescription drugs. Insight would be forced to immediately reduce or discontinue these and other discounted prescription programs without 340B Program savings.

72. If Insight is terminated from the 340B Program effective October 1, 2023, Insight will have to transfer hundreds, if not thousands, of patients to other hospitals or pharmacies, which very well may refuse to take them. Insight leadership has arranged to have 100 staff members ready on Monday, October 2, to start calling patients to tell them that Insight cannot afford to give them their prescription drugs come Monday, and that Insight will have to transfer their care to another hospital or pharmacy. These staff members have to review the 9,700 patient encounters Insight had this past quarter, call each patient, explain that Insight cannot afford their medications, and tell them that we will have to transfer their care to another provider. These calls are likely to cause an uproar in the community and irreparably damage the reputation of the hospital.

CAUSES OF ACTION

Count I – Declaratory Judgment and Injunctive Relief

73. Plaintiff re-alleges and incorporates by reference all previous allegations of this Complaint as if the same were fully set forth in this paragraph.

74. Insight seeks a declaration, pursuant to 28 U.S.C. § 2201, that Defendants lack authority to terminate Insight – a disproportionate share hospital eligible to participate in the Section 340B Program as a “Covered Entity” under only subparagraph (L) of paragraph (4) (*i.e.*,

42 U.S.C. § 256b(a)(4)(L)) – from the 340B Program for a purported failure to recertify its eligibility or update its information on the Secretary’s website.

75. Specifically, Insight does not receive assistance under federal HIV programs (subparagraph (J) of paragraph (4)) or funds for treating sexually transmitted diseases (subparagraph (K) of paragraph (4)), such that Insight is not a Covered Entity subject to the recertification process under the plain terms of 42 U.S.C. § 256b(a)(7)(A).

76. In addition, termination from the Section 340B Program is not an authorized remedy under 42 U.S.C. § 256b(d)(2)(B)(v) for (i) an alleged untimely recertification; or (ii) an alleged failure to update information on the Secretary’s website annually.

77. In the alternative, assuming, *arguendo*, that Insight is required to recertify its Section 340B eligibility, Insight seeks a declaration, pursuant to 28 U.S.C. § 2201, that Defendants failed to comply with the requirement in Section 340B that a Covered Entity be allowed a full year within which to recertify its eligibility for Section 340B.

78. Specifically, the Section 340B statute, 42 U.S.C. § 256b(a)(7)(E), provides, “The Secretary shall require the recertification of entities certified pursuant to this paragraph **on a not more frequent than annual basis. . . .**” (Emphasis added.)

79. Insight most recently completed its recertification for the Section 340B Program on September 19, 2022.

80. Therefore, under 42 U.S.C. § 256b(a)(7)(E), Insight would not have been required to complete its 2023 recertification under the Section 340B Program before September 19, 2023.

81. The Secretary and the Administrator, however, required that Insight complete its Section 340B recertification on or before September 11, 2023 – eight (8) days prior to the one-year anniversary of Insight’s previous recertification on September 19, 2022.

82. The Secretary and the Administrator, through their agents, subsequently impeded Insight's efforts to recertify under the Section 340B Program after September 11, 2023, and have since taken the position that Insight will be terminated from the Section 340B Program effective October 1, 2023.

83. There exists a justiciable case of actual controversy between the parties regarding whether Insight had until September 19, 2023 (not September 11, 2023) to recertify its eligibility in the Section 340B Program.

84. Defendants contend that Insight failed to recertify under the Section 340B Program in a timely basis and, therefore, will be terminated from the program as of October 1, 2023; whereas Insight contends that it was not required to recertify at all. At the very least, even if Insight were required to recertify its eligibility, Insight had an additional eight (8) days to complete the recertification process, during which time Defendants rendered it impossible to do so.

85. The Court should enter a declaratory judgment holding that Defendants lack authority to terminate Insight from the 340B Program for a purported failure to recertify its eligibility or update its information on the Secretary's website. Alternatively, the Court should enter a declaratory judgment holding that (i) Insight had until September 19, 2023, to recertify its eligibility in the Section 340B Program; (ii) it was, therefore, improper for Defendants to impede Insight's efforts to recertify under the Section 340B Program between September 11, 2023 and September 19, 2023; (iii) as a result, Insight shall have an additional eight (8) days to complete the recertification process under Section 340B; and (iv) provided that Insight so completes the recertification process, it shall continue to be enrolled in the Section 340B Program without interruption.

86. The Court should also grant injunctive relief to preserve the status quo, namely Insight's continuous enrollment in the Section 340B Program.

87. Insight will suffer irreparable harm unless Defendants' efforts to terminate Insight from the Section 340B Program by (i) attempting to do so without statutory authority; and (ii) improperly shortening the recertification process to less than one year – contrary to the express terms of 42 U.S.C. § 256b(a)(7)(E) – are enjoined. There exists no remedy at law than can prevent this irreparable harm.

88. Absent injunctive relief, on October 1, 2023, Insight will be ineligible to participate in the Section 340B Program and will suffer harms that cannot be rectified by simply reapplying to HRSA at the next available opportunity. Specifically, Insight will be forced to sharply curtail vital health care services and abandon some of its services to make up for the approximately \$1 million deficit in its budget if it is unable to obtain drugs at the Section 340B discount rates. This will result in the at-risk patient population Insight serves experiencing decreased access to health care. It will also cause Insight to suffer damages to its reputation and good will.

89. Insight cannot be made whole following Defendants' unauthorized exercise of authority and failure to comply with the one-year timeframe for recertification required under 42 U.S.C. § 256b(a)(7)(E). Insight is not seeking monetary damages, as there is no traditional legal remedy that would be adequate in place of the issuance of an injunction. Moreover, there is no available administrative remedy available to Insight in Section 340B for recertification matters. Without injunctive relief, therefore, Insight will have no remedy at all.

90. Because Defendants (i) had no authority to terminate Insight for a purported failure to recertify its eligibility under Section 340B or update its information on the Secretary's website; and (ii) shortened the Section 340B recertification process for Insight to less than one year in plain

violation of 42 U.S.C. § 256b(a)(7)(E), there is a substantial likelihood that Insight will succeed on the merits.

91. The balance of equities and public interest considerations weigh heavily in favor of granting injunctive relief. Unlike many other government programs, the Section 340B Program does not involve any government expense – the Secretary does not provide grants or reimbursement to Insight under the program, so no federal funds are at risk.

92. Moreover, allowing Insight to complete its recertification process without interruption to its participation in the Section 340B Program will benefit the public interest. Otherwise, Insight will be denied the drug cost savings under Section 340B, resulting in decreased access to prescription drugs and an overall decline in available health care services for the uninsured, isolated, or medically vulnerable population Insight serves.

Count II - Mandamus

93. Plaintiff re-alleges and incorporates by reference all previous allegations of this Complaint as if the same were fully set forth in this paragraph.

94. The Section 340B statute mandates the Secretary to “**require** the manufacturer offer each Covered Entity covered outpatient drugs for purchase at or below the applicable ceiling price.” 42 U.S.C. § 256b(a)(1) (emphasis added).

95. Secretary Becerra, therefore, has a non-discretionary duty pursuant to 42 U.S.C. § 256b(a)(1) to maintain Insight’s participation in the 340B Program.

96. As Insight is a Covered Entity because it is a disproportionate share hospital, and no grounds exist to disqualify Insight from 340B, Insight must be offered “outpatient drugs for purchase at or below the applicable ceiling price.” 42 U.S.C. § 256b(a)(1)

97. Under 42 U.S.C. § 256b(a)(1), Insight has a right to the performance of Secretary Becerra's duty.

98. Insight has no other adequate remedy available. Insight cannot be made whole if it is terminated from the 340B Program. Insight is not seeking monetary damages, as there is no traditional legal remedy that would be adequate in place of the issuance of an injunction and/or writ of mandamus. Moreover, there is no available administrative remedy available to Insight in Section 340B for recertification matters. Without injunctive relief and/or mandamus, therefore, Insight will have no remedy at all.

99. Under 28 U.S.C. § 1361 and 28 U.S.C. § 1651, this Court is empowered to issue a writ of mandamus, to which Insight is entitled, directing Secretary Becerra to maintain Insight's participation in the Section 340B Program on and after October 1, 2023.

PRAYER FOR RELIEF

WHEREFORE, for the foregoing reasons, Plaintiff requests the following relief:

1. A declaratory judgment declaring that, pursuant to 42 U.S.C. § 256b(a)(7)(A) and 42 U.S.C. § 256b(d)(2), Defendants lack authority to terminate Insight from the 340B Program for a purported failure to recertify its eligibility or update its information on the Secretary's website.

2. Alternatively, a declaratory judgment declaring that:

a. pursuant to 42 U.S.C. § 256b(a)(7)(E), Insight had until September 19, 2023, to recertify its eligibility in the Section 340B Program;

b. it was, therefore, improper for Defendants to impede Insight's efforts to recertify under the Section 340B Program between September 11, 2023 and September 19, 2023;

c. as a result, Insight shall have an additional eight (8) days to complete the recertification process under Section 340B; and

d. provided that Insight so completes the recertification process, Insight shall continue to be enrolled in the Section 340B Program without interruption.

3. Injunctive relief:

a. enjoining Defendants from terminating Insight from the Section 340B Program on or around October 1, 2023; and

b. directing Defendants to provide Insight an additional eight (8) days to complete the recertification process under Section 340B.

4. A writ of mandamus and/or writ(s) necessary or appropriate:

a. directing Secretary Becerra to maintain Insight's participation in the Section 340B Program on and after October 1, 2023.

5. Such other relief that the Court deems appropriate in the interest of justice.

Dated: September 29, 2023

Respectfully submitted,

EPSTEIN BECKER & GREEN, P.C.

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***Pro hac vice applications forthcoming*